

JUL 19 2001

K011501

Ethicon Endo-Surgery, Inc.  
510(k) Premarket Notification for ENDOPOUCH™ RETRIEVER™

## ENDOPOUCH™ RETRIEVER™ 510(k) Summary of Safety and Effectiveness

**Company:**

Ethicon Endo-Surgery, Inc.  
4545 Creek Rd.  
Cincinnati, OH 45242

**Contact:**

Name: Doug Kentz  
Title: Regulatory Affairs Associate II

**Date Prepared:**

May 15, 2001

**Name of Device:**

Trade Name: ENDOPOUCH RETRIEVER Specimen Retrieval Bag  
Classification Name: Laparoscope, General & Plastic Surgery

**Predicate Devices:**

ENDOPOUCH PRO Specimen Retrieval Bag, cleared under K981579 on July 9, 1998.  
Auto Suture™ ENDO CATCH™ Disposable specimen pouch, cleared under K922123 on February 1, 1993.

**Device Description:**

The ENDOPOUCH RETRIEVER Specimen Retrieval Bag is comprised of a flexible plastic bag with a large, easily accessible opening, a push/pull rod with thumb and ring handle, finger rings, and an introducer tube. The thumb ring handle and finger rings allow for single-handed deployment of the specimen bag within the body cavity. In the fully deployed condition, the bag opening is maintained in a fully open position by a metallic rim. A string with a slipknot facilitates closure of the specimen bag after the specimen has been collected.

**Intended Use:**

The ENDOPOUCH RETRIEVER Specimen Retrieval Bag is a disposable device used as a receptacle for the collection and extraction of tissue specimens such as the appendix, gall bladder, ovaries, fibroid tumors, other tissues and calculi during laparoscopic surgical procedures.

May 15, 2001

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 19 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Doug Kentz  
Regulatory Affairs Associate II  
Ethicon Endo-Surgery, Inc.  
4545 Creek Road  
Cincinnati, Ohio 45242

Re: K011501

Trade/Device Name: ENDOPOUCH™ RETRIEVER™ Specimen Retrieval Bag  
Regulation Number: 876.1500  
Regulatory Class: II  
Product Code: GCJ  
Dated: May 15, 2001  
Received: May 16, 2001

Dear Mr. Kentz:

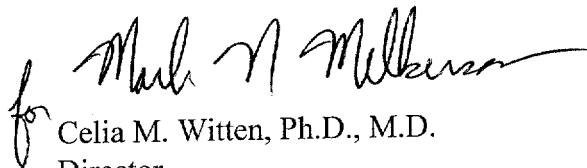
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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510(k) Number (if known): K011501

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Indications for Use:

**The ENDOPOUCH RETRIEVER Specimen Retrieval Bag is a disposable device used as a receptacle for the collection and extraction of tissue specimens such as the appendix, gall bladder, ovaries, fibroid tumors, other tissues and calculi during laparoscopic surgical procedures.**

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

*for Mark A. Miller*  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K011501